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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,708	09/26/2001	Markus Heil	Le A 34 813	8172

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EXAMINER

WRIGHT, SONYA N

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 07/16/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/965,708

Applicant(s)

HEIL ET AL.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 9-11 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-7 and 9-11 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by STN

International® CAPLUS Database, Accession No. 1991:514130; Fujisawa

Pharmaceutical Co., Ltd., Japanese Patent JP03056431 (1991), abstract.

Applicant claims phenoxyphenyl alkanesulphonates which are useful in treating neurodegenerative disorders. The prior art teaches biphenyl compounds which are useful as analgesics, antirheumatics, and blood platelet promoters. The prior art teaches the instant claims when, in the instant claims, R1 is hydrogen, R2 is nitro, R3 is methyl or trifluoromethyl, R4 is hydrogen, and A is oxygen. See RN 135209-90-4 and RN 135210-08-1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, are rejected under 35 U.S.C. 103(a) as being unpatentable over STN International® CAPLUS Database, Accession No. 1991:514130; Fujisawa Pharmaceutical Co., Ltd., Japanese Patent JP03056431 (1991), abstract.

Determination of the scope and content of the prior art (MPEP §2141.01)

The prior art teaches biphenyl compounds which are useful as analgesics, antirheumatics, and blood platelet promoters. The prior art teaches the instant claims when, in the instant claims, R1 is hydrogen, R2 is nitro, R3 is C4-C7 alkyl which may be substituted one or more times by fluorine or chlorine, R4 is hydrogen, and A is oxygen. See species examples RN 135209-90-4 and RN 135210-08-1.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

In claim 2, R3 denotes n-butyl, and n-pentyl. The prior art teaches a homolog of the compounds of claim 2 in example RN 135209-90-4, by teaching a methane group in place of the n-butyl and n-pentyl groups of claim 2.

In claim 2, R3 denotes 4,4,4-trifluorobut-1-yl or 5,5,5-trifluoropent-1-yl. The prior art teaches a homolog of the compounds of claim 2 in example RN 135210-08-1, by teaching a trifluoromethane group in place of the 4,4,4-trifluorobut-1-yl or 5,5,5-trifluoropent-1-yl groups.

In claim 3, there is a hydrogen atom in position 4 of the phenyl ring substituted by R1 and R2. The prior art teaches a positional isomer of the compounds of claim 3 in examples RN 135209-90-4 and RN 135210-08-1. In the prior art there are hydrogens in positions 2, 3, 5, and 6 and not in position 4, as in instant claim 3.

In claim 4, R1 and R2 occupy positions 2 and 3 on the phenyl ring. The prior art teaches a positional isomer of the compounds of claim 4. In the prior art, in examples

RN 135209-90-4 and RN 135210-08-1, R2 is nitro and it occupies position 4, not position 2 or 3, as in instant claim 4.

In claim 5, A is in position c of the benzene radical. The prior art teaches a positional isomer of the compounds of claim 5. In the prior art, in examples RN 135209-90-4 and RN 135210-08-1, nitrogen (which corresponds to A in the instant claims) is in the 4-position on the phenyl, not in the c position as in instant claim 5.

Finding of prima facie obviousness---rational and motivation (MPEP §2142-2143)

To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. In re Henze, 85 USPQ 261 (1950). The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare homologs of the compounds taught in the reference with the expectation of obtaining compounds which could be used in pharmaceuticals. Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Further, one of ordinary skill in the art would be motivated to prepare the instant compounds because nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer, as taught by Applicants, since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results. In re Norris, 84 USPQ 458 (1950).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1626

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 10 and 11 are directed to "a method of . . . preventing states of pain and/or neurodegenerative disorders" and a method of . . . preventing Parkinson's disease". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There are a vast number of neurodegenerative disorders, including Parkinson's disease, and Applicant does not give support for "preventing" all

forms of neurodegenerative disorders. The art pertaining to neurodegenerative disorders remains highly unpredictable. The various forms of these disorders have different causative agents, involve different cellular mechanisms, and, consequently, differ in treatment protocol. Therefore, based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not use the claimed invention without undue experimentation.

It is suggested that Applicant delete "preventing" from claims 10 and 11 and that in claim 10, Applicant incorporate into claim 10, the states of pain and neurodegenerative disorders that are supported in the specification, e.g., on pages 16-18, in order to obviate the rejection under 35 U.S.C. 112 first paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is drawn to medicaments. However, it is unclear what subject matter Applicant intends to claim through the use of the term. It is suggested that Applicant delete "medicament" and insert —composition—in order to obviate the rejection under 112 second paragraph.

Claim 10 contains the term "and/or" which renders the claim indefinite. It is not clear whether claim 10 is drawn to methods of treating both states of pain and

neurodegenerative disorders, or whether the claim is drawn to treating only one of the conditions.

Claim Objections

Claims 3, and 4 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claims 7 is objected to because of the following informalities: Claim 7 is a compound claim which is dependent on a process claim. Claim 7 should be amended to depend from a compound claim.

Allowable Subject Matter

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

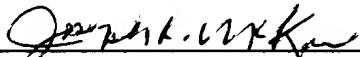
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for

draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.



Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

July 11, 2002